## Lawrence, Susan

**From:** Tomasino, Stephen
**Sent:** Tuesday, November 03, 2015 6:56 AM
**To:** Lawrence, Susan
**Subject:** FW: EOS and Cupron Protocol comments upon Bactericidal Activity of Hard Non Porous Copper and Copper Alloy Surfaces

Another set of comments...in email, not attached...

**From:** Perry, Mark
**Sent:** Friday, November 14, 2014 2:55 PM
**To:** Tomasino, Stephen <Tomasino.Stephen@epa.gov>
**Subject:** FW: EOS and Cupron Protocol comments upon Bactericidal Activity of Hard Non Porous Copper and Copper Alloy Surfaces

Steve, Cupron's copper comments...

**From:** Alastair Monk [mailto:amonk@cupron.com]
**Sent:** Friday, November 14, 2014 2:51 PM
**To:** Perry, Mark
**Cc:** kgt@eos-surfaces.com; candrews@cupron.com
**Subject:** EOS and Cupron Protocol comments upon Bactericidal Activity of Hard Non Porous Copper and Copper Alloy Surfaces

Dear Mr Perry

Cupron Inc and EOS surfaces have reviewed the proposed protocol "Protocol for the Evaluation of Bactericidal Activity of Hard, Non-porous Copper/Copper-Alloy Surfaces" posted for public comment on 09/19/2014 available at http://www.epa.gov/oppad001/regpolicy.htm.
We support the EPA's efforts in producing data of the highest quality to support Public Health claims, and to provide consumer confidence in those claims and their substantiation. Based upon our review of the proposed protocol we have the following comments outlined below, and provide these comments to you to assist in making sure that the protocol meets and reflects current protocols and standards, and reflects the current market applicability of the surfaces the proposed protocol refers to.

1) **Addition of a test microbe**
The proposed protocol has increased the number of required test organisms compared to previously approved Agency protocols from two organisms to three with the addition of *P. aeruginosa* (ATCC 15442). Based upon the scientific literature it has been shown that gram negative bacteria persist longer on fomites than gram positive bacteria (1) , however gram positive bacteria are more easily transferred to the hands of healthcare workers (2). Due to the potential use of the hard surface in a nosocomial or hospital setting the test organisms should represent a gram negative and a gram positive organism to mimic the durability of gram negative organisms on a surface and to represent the higher rate of transfer to healthcare worker hands of gram positive organisms. Based upon the CDC's incidence of organisms causing hospital acquired infections (3) the most frequent gram positive organism is *S. aureus* and the most frequent gram negative organisms are *E. coli and P. aeruginosa.* Due to *P. aeruginosa* being a more frequent environmental pathogen than *E. coli* the protocol should require only *S. aureus* and *P. aeruginosa* as representative organisms of gram positive and gram negative bacteria. The use of these two organisms would also be in keeping with the EPA's currently required standards for antimicrobial

products used in a hospital setting with Public Health claims to demonstrate efficacy against *S. aureus* and *P. aeruginosa* as located here:- http://www.epa.gov/oppad001/antimicrobial-testing-program.html.

2) **Chemical Treatments**

In accordance with the typical use pattern of the material to be registered utilizing the proposed protocol, abrasion can occur both under moist and dry conditions. This has previously been explored in the EPA approved protocol "Test Method for Residual Self Sanitizing Activity" (4) and protocol 01-1A "Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces" (5). The protocol should be amended to reflect not only dry abrasion but also wet abrasion cycles in order to closely follow the real world use and treatment of the material to be registered. The order of this activity should be amended to follow current best practices in hospitals which consists of daily disinfection (chemical treatment) followed by 24 hours of use and wear (abrasion cycles). This typical use pattern of cleaning and daily activities, or in the protocol what would be apply test product, wear cycle dry, apply test product, wear cycle wet to be completed on an ongoing basis until the end of the chemical treatment/wear cycles to initiate the sanitizer test would be a more similar situation to the daily cleaning regimes experienced in most healthcare facilities.

The EPA should also update the choice of chemical agents to be agents that are currently utilized in the use pattern setting i.e. hospitals, and also recommended by current environmental cleaning guidelines. The CDC publication "Guidelines for Environmental Infection Control in Health Care Facilities" (6) states that for Cleaning of blood and Body Substances a disinfectant on List C, D or E of the EPA's Registered Antimicrobial Products should be used. EDTA/ Phosphoric acid is not listed on D or E, and is listed only twice on List C. In addition it is Cupron and EOS' understanding that the leading antimicrobial products utilized in a hospital setting are hydrogen peroxide, sodium hypochlorite and quaternary ammonium based disinfectants. There is also only a single mention of phosphoric acid as a disinfectant in the CDC publication "Guidelines for Disinfection and Sterilization in Healthcare Facilities 2008" (7). This reference to phosphoric acid is at 0.85% (10x lower than the proposed protocol concentration) and is used to lower the pH of the disinfecting solution. There is no mention of the use of phosphoric acid in combination with EDTA as a disinfectant or sanitizer. Quaternary ammonium compounds (Quats) are however reviewed as "widely used disinfectants" (7). Whilst phosphoric acid and EDTA can be used as additional formulants for disinfectant products, the EPA should update the protocol to represent the most appropriate cleaning agents in current use for the proposed protocol, therefore removing EDTA/Phosphoric acid as a separate cleaning agent and replacing this solution with the specification that an EPA registered quaternary ammonium based cleaning agent with approval for use on a hard surface as a spray application (as with Solution A and B) should be used. The use of an EPA registered quaternary ammonium based disinfectant agent should be used as this would standardize the protocols selection of disinfectants from only EPA registered agents, would more accurately represent the current use of cleaning agents in the use setting, and would still account for compounds such as phosphoric acid/EDTA used in the formulation of end products.

3) **Contact time**

Hospital cleaning practices are currently daily cleaning (8), with further cleaning as required due to contamination events or terminal cleans upon patient's room becoming available. In light of this cleaning regime a contact time of 2 hours is appropriate. 120 minutes is appropriate as this can be the contact time in the case of other germicidal agents such as Virkon (7), and due to the continuous activity of the permanently present hard surface the residual contact time can be 120 minutes as the material will act as a residual sanitizing agent. In addition the contact time should begin after a suitable drying time on the test pieces in order to allow for the bacteria and organic material in the inocula that has been spread over the surface to settle and contact the surface in order to validate the contact efficacy of the material in the specified time frame in the presence of organic material. The protocol should be updated to include a drying time as previously proposed of 20-40 minutes. Whilst the antimicrobial efficacy of the product will begin immediately upon inoculation the use of a drying time would be more similar to the real world contamination of a surface, with bacteria settling upon a surface, after which time the efficacy of the product should be assessed.

4) **Data to be recorded**

The EPA should remove all requests relating to the visual appearance of the material post cleaning regimes and prior to testing, as the end point of this protocol is bacterial efficacy assessment. The recording of the visual attributes with no visual scale provided, or standard methodology in order to measure change from baseline is arbitrary and the results cannot be standardized between observers, not to mention potentially unreproducible and is an unnecessary testing requirement burden. In line with other efficacy protocols the assessment of this protocol is a pass rate of the efficacy end point not a visual change.

5) **Claim Language**
In order to standardize the Public Health claim language the claim language should be changed to killing "greater than" 99.9% of bacteria rather than the current "at least". As the Agency is aware public health claims have traditionally been granted with label claims representing greater than language for numerous products and any product registered under the proposed protocol should reflect such language.

6) **Protocol specificity**
Cupron would request changes in the protocol as outlined above including examples such as the wear testing and removal of the phosphoric acid/EDTA as a cleaning agent in order to greater diversify the protocols applicability to hard surface antimicrobial technologies outside of copper or copper alloys. Whilst the registrants of surfaces with Public Health claims are currently copper alloys or copper based technologies this protocol should represent the standard protocol for all antimicrobial technologies wishing to be incorporated into surfaces and to demonstrate effectiveness to substantiate public health claims. As the protocol stands currently it penalizes the current registrants as some attributes of the protocol outlined in this letter specifically address efficacy of only copper products. Cupron and EOS would wish this protocol and standards to be the required protocol and efficacy standard for all surface antimicrobial registrants wishing to make public health claims relating to bacterial sanitization.

If you could kindly confirm receipt of this email I would appreciate it, and if any of the information provided in this response requires further discussion or clarification Cupron and EOS would request a face to face meeting with the Agency to facilitate the discussion.

References


1. Kramer A et al, How long do nosocomial pathogens persist on inanimate surfaces? A systematic review. *BMC Infectious Diseases* 2006, ***6***:130
2. Filho PPG et al, Survival of gram-negative and gram-positive bacteria artificially applied on the hands. J.Clin.Microbiol. 1985, 21 (4) 652
3. Hidron AI et al, Antimicrobial-Resistant Pathogens Associate with Hospital Acquired Infections; Annual Summary of Data Reported to the National Helathcare Safety Network at the Centers for Disease Control and Prevention 2006-2007. ICHE. 2008, Nov 29:11
4. Test Method for Residual Self Sanitizing Activity of Cupron Enhanced Hard Surfaces (HS01). (On file at the EPA)
5. Protocol #01-1A "Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces". (http://www.epa.gov/oppad001/cloroxpcol_final.pdf)
6. Guidelines for Environmental Infection Control in Health-Care Facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). (http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_hcf_03.pdf)
7. Rutala WH, Weber DJ and the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. (http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf )
8. Keeping your hospital room clean. APIC 9/1/2009 (http://www.apic.org/For-Consumers/Monthly-alerts-for-consumers/Article?id=keeping-your-hospital-room-clean)

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